

**REMARKS**

**I. Status of the Claims**

After entry of this Amendment, claims 1-25, and 29-33 will be pending and under examination. Claim 1 is amended to incorporate the subject matter of claim 2, and claim 2 is amended to recite that the pH is 10.3. Support for this amendment is found, for example in the as-filed specification at page 7, lines 20-21. Claim 6 is amended to clarify the Markush group recited (see M.P.E.P. 2173.05(h)) and to address the Office's concern indicated at page 2 of the Office Action. Claim 8 is amended to correct informalities. Claim 19 is amended to correct the typographical error addressed by the Office on page 2 of the Office Action. Claims 21-23 are amended to correct for dependency.

Without prejudice or disclaimer, claims 27 and 28 are cancelled and the subject matter contained therein is incorporated into new claims 31 and 32, which recite methods for producing a medical solution. New claim 33 is added to recite a method for producing a medical solution, with exemplary support found in the as-filed specification at page 9, lines 15-18.

Accordingly, no new matter has been added by these amendments.

**II. Rejection under 35 U.S.C. § 112**

In the office action, the Examiner rejects claims 21-23 and 29-30 under 35 U.S.C. § 112, second paragraph, as being indefinite. (Office Action at page 3.) The Examiner contends that because claims 21-23 recite methods, but depend upon claims 27 and 28 which recite solutions, that "claims 21-23 have improper dependency." (*Id.*)

Claims 27 and 28 are cancelled herein and rewritten as new claims 31 and 32, and new claims 31 and 32 are directed to methods for producing a medical solution. Thus, claims 21-23, directed to methods, now have proper dependency, thereby rendering this rejection moot. Applicant respectfully requests the withdrawal of this rejection.

**III. Rejection under 35 U.S.C. § 103**

**A. Zander and Duponchelle**

In the Office Action, the Examiner rejected claims 1-7, 11-14, 16-17, 20 and 24 under 35 U.S.C. § 103(a) as unpatentable over "Zander" (U.S. Patent No. 5,296,242, to Zander) in view of "Duponchelle" (U.S. Patent No. 6,309,673, to Duponchelle). (Office Action at page 4.) The Examiner contends that Zander discloses "two separately stored single solutions to be combined prior to use wherein one is bicarbonate-free acid solution and the other is a bicarbonate-containing alkaline solution." (Office Action at page 6 (emphasis omitted).) The Examiner concedes, however, that "Zander does not teach the instantly claimed pH values . . . the addition of electrolytes to the bicarbonate solution . . . a multi-compartment bag . . . [and] does not specify the acid HCl," and cites Duponchelle to remedy Zander's deficiencies. See *id.* Applicant respectfully disagrees and traverses this rejection.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. Moreover, the Examiner has the burden to at least demonstrate (1) a finding that there is some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference

teachings; and (2) a finding that there was a reasonable expectation of success to make the proposed modification. See M.P.E.P. § 2143(G). Moreover, to establish a *prima facie* case of obviousness, the Examiner has the burden of establishing that the prior art references teach or suggest all the claim limitations. See *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Applicant respectfully submits that the Examiner has not met this burden, and thus, has failed to establish a *prima facie* case of obviousness over the cited references.

As described in the specification at page 1, bicarbonate solutions used as buffers for medical solutions in dialysis presents known problems in the art including loss of carbon dioxide resulting in the increase of pH up to 9-10.5. (See Applicant's Specification at page 1, lines 9-32.) Zander also teaches that carbon dioxide loss leads to bicarbonate solutions that "are not stable," and that "it must be ensured that no CO<sub>2</sub> escapes so that the composition of the bicarbonate-containing alkaline solution does not change during storage." (Zander at col. 1, ll. 10-14 and 40-43.) In contrast, Duponchelle teaches that which is explicitly taught away in both the present application and in Zander, despite the known problems with CO<sub>2</sub> escaping from bicarbonate solutions and a subsequent change in composition of the solution. For example, Duponchelle teaches that:

the pH of the bicarbonate-based concentrate is chemically adjusted to about 8.6, **and allowed to adjust further over time during storage. The inherent instability of the concentrate effectively increases the pH with time and storage due to carbon dioxide loss until it reaches a steady state level of about 9 to 10.** The pH naturally rises during storage when the solution is housed in a gas permeable container. However, the initial adjustment allows to obtain a pH in a physiological range (6.5-7.6) after mixing.

(Duponchelle at col. 4, ll. 58-67 (emphasis added).) As discussed above, Zander discourages storing biocarbonate containing solutions in a manner that allows CO<sub>2</sub> to escape over time such as the gas-permeable container taught in Duponchelle. (Zander at col. 6, ll. 50-55 and Figure 1.) Considering the known drawbacks associated with CO<sub>2</sub> release from biocarbonate-containing solutions for dialysis, one of ordinary skill in the art would have had no motivation to look to Duponchelle to modify the solution of Zander in the first place. As such, the prior art fails to motivate one of ordinary skill in the art to combine the two teachings.

Applicant respectfully submits that even if one of ordinary skill in the art were to combine Zander and Duponchelle, despite their conflicted teachings, they still would not have been guided to the presently claimed invention. Neither Zander nor Duponchelle teach or suggest an alkaline solution having a pH of 10.1-10.5. (See *e.g.*, Applicant's claim 1, as-amended.) Zander suggests an alkaline solution with a pH of 9.4 (col. 6, ll. 35-39) and nowhere teaches or suggests increasing its pH, for example, to the claimed pH range. And as discussed above, Duponchelle teaches that its bicarbonate concentrate "is adjusted to a range of about 8.6 to 10.0." (Duponchelle at col. 5, ll. 22-24.) Duponchelle also teaches that a bicarbonate-containing solution with a higher pH, for example a pH of 11, will eventually decrease over time to a pH range of 9-10. Duponchelle at col. 8, ll. 28-34 (referring to Figure 2). Thus, even if one of ordinary skill in the art would have been motivated to modify the pH level of Duponchelle's bicarbonate-containing solution to the claimed range, any higher pH would not remain based on Duponchelle's permeable gas container, but instead, would decrease over time to a pH range of 9-10. As a result, the concentration of bicarbonate in

Duponchelle's alkaline solution is also unstable. In order to maintain a stable concentration, bicarbonate would necessarily need to be added to the final solution to keep it within a specific range after mixing with the acidic solution. (See Applicant's Specification at page 2, ll. 13-18.)

In contrast, the presently claimed medical solutions are stable over time, including the pH and bicarbonate concentration of the alkaline solution. This is due to "the partial pressure of carbon dioxide, CO<sub>2</sub>, in the first single solution" being "the same order of magnitude as the partial pressure of carbon dioxide, CO<sub>2</sub>, of the atmosphere . . . ." (Applicant's Specification at page 3, ll. 14-19.) The alkaline solutions in accordance with the present invention have a stable pH distinctive from Duponchelle, which to the contrary relies upon either self-adjusting the pH of the solution or directly adjusting the pH by adding a physiologically acceptable base to the aqueous solution containing sodium bicarbonate. (Duponchelle at col. 4, line 58 to col. 5, line 5.) Preparing solutions in accordance with the present invention results in more stable solutions over time with no need to adjust the pH and bicarbonate concentration, such as described in Duponchelle. In addition, among the bases Duponchelle discloses as suitable for raising the pH of the bicarbonate solution, "sodium hydroxide, potassium hydroxide, calcium hydroxide, and magnesium hydroxide," (Duponchelle at col. 7, ll. 29-32), some bases are difficult to dissolve and calcium, magnesium, and potassium ions are highly restricted in amount added in a dialysis fluid or substitution fluid. Thus, adding these types of bases to solutions to adjust pH would highly jeopardize the final concentrations of the amount of calcium, magnesium and potassium ions.

Therefore, while there is no reason why one of ordinary skill in the art would have combined Zander and Duponchelle based on their conflicted teachings, even if one of skill in the art did make such a combination, there would have been no reasonable expectation of successfully achieving the instantly claimed medical solutions, without the benefit of impermissible hindsight. See M.P.E.P. § 2142. Effective September 1, 2010, the U.S. Patent and Trademark Office issued a "2010 KSR Guidelines Update" ("Guidelines") to provide additional guidance to its personnel "to be used when applying the law of obviousness under 35 U.S.C. § 103." 75 Fed. Reg. 53643, 53643-44 (Sept. 1, 2010).

Under Section 4A of the Guidelines, entitled "Combining Prior Art Elements," the Guidelines describe, as Example 4.2, the recent Federal Circuit decision *Crocs, Inc. v. International Trade Commission*, 598 F.3d 1294 (Fed. Cir. 2010). Regarding this case, the Guidelines state:

**The Federal Circuit's discussion in *Crocs* serves as a reminder to Office personnel that merely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness. In accordance with MPEP § 2143 A(3), a proper rejection based on the rationale that the claimed invention is a combination of prior art elements also includes a finding that results flowing from the combination would have been predictable to a person of ordinary skill in the art. MPEP § 2143 A(3). If results would not have been predictable, Office personnel should not enter an obviousness rejection using the combination of prior art elements rationale, and should withdraw such a rejection if it has been made.**

*Id.* at 53647 (emphasis added). Because it would not have been predictable to increase the pH level of bicarbonate solution based on the teaching in the prior art, the Examiner failed to establish a *prima facie* case of obviousness over Zander and Duponchelle.

The stability of the claimed solutions is further evidenced by the experimental data presented in the Declaration under 37 C.F.R. §1.132 of co-inventor Malin ERNEBRANT ("Declaration") attached to this Response. In particular, the Declaration demonstrates stability of a bicarbonate solution over a period of 17 days, with minimal changes in pH observed. (Declaration at page 3, Table 4.) A second study provides stability data for two sets of bicarbonate, acid and mixed solutions over a period of 31 days. (Declaration at page 3.) As indicated in Table 5, there was very little deviation between sets and the final solutions had a pH close to the target pH of 7.2. In contrast to prior art methods, such as that described in Duponchelle, this can represent a significant savings in time (i.e., no need to let the bicarbonate solution self-adjust to the proper pH as disclosed in Duponchelle), safety (i.e., no need to add additional bicarbonate to the solution to maintain its concentration as disclosed in Duponchelle), resource allocation (i.e., no need to add additional base as disclosed in Duponchelle), and money, resulting in bicarbonate and final solutions with a more stable pH and bicarbonate concentration. Accordingly, this evidence is relevant to the issue of obviousness and must be considered. M.P.E.P. 2141(II).

**B. Zander, Duponchelle and Linden**

In the Office Action, the Examiner also rejected claims 8-10, 15, 18-19, 21-23, 25 and 27-30 under 35 U.S.C. § 103(a) as unpatentable over Zander in view of Duponchelle and further in view of "Linden" (International Patent Application No. WO 01/89478 to Linden et al.). (Office Action at page 12.) The Examiner concedes that Zander fails to teach "the addition of a third or fourth single solution," and "does not specify that the sterilization is heat sterilization at a temperature of at least 100°C," and

relies on Linden to remedy these deficiencies. *See id.* Applicant respectfully disagrees and traverses this rejection.

Claims 8-10, 15, 18-19, 21-23, 25 and 27-30 are ultimately dependent from claim 1 and therefore encompass all the elements recited in claim 1. The shortcomings of Zander and Duponchelle and their failure to render the instant invention obvious have already been discussed above. Linden fails to overcome these shortcomings. Rather, Linden merely exemplifies multi-compartmental containers that may include bicarbonate with no indication as to the pH of that solution. (Linden at Examples 1-5.)

Accordingly, because Linden does not remedy the shortcomings of Zander and Duponchelle, the proposed combination fails to meet the limitations of the instant claims. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

#### **IV. Double Patenting Rejection**

The Examiner also rejected claims 1-7, 11-14, 16-17, 20 and 24 on the grounds of provisional obviousness-type double patenting as unpatentable over claims 5-11, 14-17, 20 and 21 of U.S. Application No. 11/658,001 ("the '001 application"). (Office Action at page 16.) Specifically, the Examiner alleges that "both the instant application and copending '001 claim the same solutions with the same ingredients, the same pH and the same partial pressure of carbon dioxide." (Office Action at page 17.)

Applicant notes that the '001 application was filed on November 2, 2007, after the filing the date of the present application (i.e., May 7, 2007). If a "provisional" nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed



application to issue as a patent without a terminal disclaimer. M.P.E.P. § 804.

Accordingly, Applicant respectfully requests that the Examiner hold the rejection in abeyance until allowable subject matter has been identified in the present application.

**V. Conclusion**

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: January 21, 2011

By: /Aaron L. Parker/  
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**Attachment:** Declaration under 37 C.F.R. §1.132 of co-inventor Malin ERNEBRANT